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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,953	<b>Applicant(s)</b> HENNEN ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 19, 2006 has been entered. Claims 1-16 and 18-22 are pending and under examination.

***Response to Amendment***

The rejection of claims 1-3, 7-16 and 18-22 under 35 U.S.C. 102(b) as anticipated by Tokoro (US 5,080,895) is withdrawn in view of Applicant's amendment to the claims. The claims are drawn to a method for causing a treated animal to elicit a T-cell mediated immune response, comprising administering a quantity of a composition including an extract of a non-avian egg obtained from a non-avian source animal, said extract comprising transfer factor, generated by said source animal in a T-cell mediated immune response to at least one antigenic agent, in a concentration greater than that present in the egg and in a sufficient quantity to initiate said T-cell mediated immune response in the treated animal. The rejection is withdrawn because Tokoro fails to teach the production of transfer factor from non-avian eggs.

The rejection of claims 4-6 under 35 U.S.C. 103(a) as obvious over Tokoro in view of Kirkpatrick (US 5,840,700) is withdrawn in view of Applicant's amendment to the claims. The

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rejection is withdrawn because Tokoro and Kirkpatrick fail to teach the production of transfer factor from non-avian eggs.

The Office previously indicated that the embodiment of cancelled claim 17 was allowable over the prior art because Tokoro fails to teach the production of transfer factor from non-avian eggs. Upon further consideration, the following new grounds of rejection are set forth. Any inconvenience is regretted.

***Claim Rejections - 35 USC § 112***

***(New Rejection) Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*** Claim 16 is drawn to an embodiment that include avian egg extract. However, claim 16 depends from claim 1, which excludes avian eggs. The metes and bounds of the claim cannot be determined with the contradictory embodiments. Correction is required.

***Claim Rejections - 35 USC § 102***

***(New Rejection) Claims 1-3, 7-13, 15, and 18-22 are rejected under 35 U.S.C. 102(b) as anticipated by Lee (US Patent 5,367,054).*** The claims are drawn to a method for causing a treated animal to elicit a T-cell mediated immune response, comprising administering a quantity of a composition including an extract of a non-avian egg obtained from a non-avian source animal, said extract comprising transfer factor, generated by said source animal in a T-cell mediated immune response to at least one antigenic agent, in a concentration greater than that

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present in the egg and in a sufficient quantity to initiate said T-cell mediated immune response in the treated animal.

Lee discloses a method for isolating and purifying immunoglobulins or fragments thereof or other biologically active factors from non-immune or immune egg yolk extracts (abstract).

Lee's immune eggs are collected from any egg-producing member of the avian, reptile, amphibian or fish family which have been immunized (col. 4, lines 58-63). The antigens that can be used to immunize the egg-producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). Although Lee does not mention the presence of transfer factor, one would expect transfer factor to be present in Lee's eggs because the subjects are exposed to antigens that are capable of inducing a T-cell mediated immune response. Further, amphibians, reptiles and fish are exposed to a plurality of natural antigens that are present in the environment regardless of human-controlled exposure to antigens via vaccination. Lee teaches that the products purified from the eggs are for pharmaceutical purposes such as passive immunization or as a health food ingredient (col. 1, lines 29-33).

Although Lee does not mention transfer factor or its molecular weight, the presence of transfer factor in Lee's composition is expected because Lee immunized hens with antigens that induce a T-cell response, and collects the immunoglobulin from the immune eggs. The process of IgY purification concentrates the amount of transfer factor expected to be present in the immunoglobulin fraction of the immune eggs. In column 5, line 38 through col. 6, line 14, Lee describes the process of extraction and phase separation of IgY. Through the process described, IgY as well as transfer factor is expected to be present in the final product described by Lee. During ultrafiltration, the composition is filtered with a 30K molecular weight cut off. The

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resulting retentate is dried or further purified (col. 6, lines 1-5). Therefore, the claims are anticipated by Lee's disclosure.

*(New Rejection) Claims 4-6 and 14 are rejected under 35 U.S.C. 103(a) as obvious over Lee in view of Kirkpatrick (US 5,840,700).* The claims are drawn to a method of eliciting a T-cell mediated immune response in an animal by administering an extract of a non-avian egg including transfer factor formulated for application to the skin of an animal, nasal administration and parenteral administration. Specifically, the transfer factor molecules are specific for Newcastle disease virus, rubeola virus, mumps virus, rubella virus, Epstein-Barr virus, hepatitis B or *H. pylori*.

The rejection above establishes the Office's position that transfer factor was inherently present in Lee's product. Lee is silent on the routes of administration instantly claimed, however, one would have been motivated to use them with the product of Lee because Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally. Although Lee does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications. One would have been motivated to administer the transfer factor via other routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Lee would have been formulated successfully for other routes of administration because Kirkpatrick formulates transfer factor in various mediums.

Further, although Lee does not specifically mention the antigens instantly claimed, Kirkpatrick discloses the production of transfer factor specific for viruses, such as Epstein-Barr

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virus (col. 7, lines 60-67). One would have been motivated to use antigens from Epstein-Barr in Lee's method because Lee teaches that the antigens that can be used to immunize the egg-producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). One would have had a reasonable expectation of success that immunizing Lee's eggs with Epstein-Barr virus would have produced transfer factor specific for Epstein-Barr virus because Kirkpatrick produces transfer factor specific for Epstein-Barr virus with hens eggs. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen 8/25/06*  
STACY B. CHEN  
PRIMARY EXAMINER